IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MUHAMAD ALY RIFAI, M.D

Plaintiff,

v.

THE UNITED STATES DEPARTMENT OF JUSTICE et al.,

Defendants.

Case No. 5:24-CV-01242-JLS

PLAINTIFF'S RESPONSE TO THE UNITED STATES' MOTION TO DISMISS AMENDED COMPLAINT

Plaintiff, Muhamad Aly Rifai, M.D. ("Dr Rifai"), by and through undersigned counsel, hereby files Plaintiff's Response to the United States' Motion to Dismiss Amended Complaint. For the reasons that follow, Plaintiff submits that his Amended Complaint (ECF No. 17) should not be dismissed. The Court should instead deny the United States' motion.

BACKGROUND

On October 8, 2024, the Court issued an order setting the briefing schedule and ordering the parties to "focus on the applicability of the Supreme Court's decision in *Axon Enter. Inc. v. Federal Trade Commission*, 598 U.S. 175 (2023) to the facts of this case. (ECF No. 22).

On November 1, 2024, the Government filed its Motion to Dismiss Amended Complaint, asking that the Court dismiss, with prejudice, Plaintiff's pending Amended Complaint. (ECF No. 24). That motion argues that dismissal is appropriate because there is no DEA final agency action for the Court to review. (*Id*. at 4). According to the Government, this means that Dr. Rifai lacks standing and that this Court lacks subject matter jurisdiction. (*Id.)*. Further, the Government

contends that Rifai's claims do not qualify for district court jurisdiction under the *Thunder Basin* factors and the *Axon* decision. (*Id*.). Dr. Rifai now files a response to the Government's Motion to Dismiss Amended Complaint.

LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(1) authorizes a district court to dismiss a case where there is a lack of subject matter-jurisdiction, which requires the existence of "cases or controversies" under Article III of the U.S. Constitution. *See, Whitmore v. Arkansas*, 495 U.S. 149, 154–55 (1990). The "cases or controversies" requirement includes the following: injury in fact, causation, and redressability. *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 103 (1998).

For a plaintiff to establish an "injury-in-fact" he must set forth an injury that is concrete in both a qualitative and temporal sense. *Whitmore*, 495 U.S. at 155. Plaintiff's complainant must allege an injury to himself that is "distinct and palpable," as opposed to merely "[a]bstract," and the alleged harm must be actual or imminent, not "conjectural" or "hypothetical." *Id*. To satisfy "causation," the plaintiff must establish that his injury can "fairly be traced to the challenged action." *Id*. Finally, "redressability" is satisfied where the plaintiff can establish that his injury is likely to be redressed by a favorable decision. *Id*. Speculation on the scope of redressability will not do. *See Id*. Even if a plaintiff satisfies these three requirements, however, dismissal is appropriate if there is a lack of subject matter jurisdiction. *See, Steel Co*., 523 U.S. at 88–89.

ARGUMENT

I. DR. RIFAI'S CONSTITUTIONAL CLAIMS ARE REVIEWABLE UNDER THE SUPREME COURT PRECEDENT IN *AXON*

The Government contends that any claims brought under the Administrative Procedure Act ("APA") must be dismissed because there is no final agency action ripe for review by the Court. (ECF No. 24, at 13). Dr. Rifai does not concede that there has been no DEA Final Agency Action,

but rather argues that the Court does not need to consider this in determining whether there is subject matter jurisdiction over his claims due to the precedent set forth in *Axon*.

Section 706(2) authorizes a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2). The APA "provide[s] a limited cause of action for parties adversely affected by agency action," *Chehazeh v. Att'y Gen. of U.S.*, 666 F.3d 118, 125 n.11 (3d Cir. 2012) (internal quotation omitted). That agency actions must be a "final agency action for which there is no other adequate remedy in a court" and without which a plaintiff "cannot state a claim under the APA[.]" 5 U.S.C. § 704; *Chehazeh*, 666 F.3d at 125 n.11.

The Supreme Court has recognized that "[a] special statutory review scheme [] may preclude district courts from exercising jurisdiction over challenges to federal agency action." *Axon Enter. v. FTC*, 598 U.S. 175, 185 (2023) ("We have several times held that the creation of such a review scheme for agency action divests district courts of their ordinary jurisdiction over the covered cases."). Here, that statutory scheme is the APA, 5 U.S.C. § 704, and the codified causes of action in 5 U.S.C. § 706.

"But a statutory review scheme of that kind does not necessarily extend to every claim concerning agency action." *Axon*, 598 U.S. at 185. The Supreme Court has instead identified three considerations—commonly known as the *Thunder Basin* factors—to determine whether claims concerning agency action are "of the type Congress intended to be reviewed within th[e] statutory structure." *Id*. at 176. (citation omitted). First, could precluding district court jurisdiction "foreclose all meaningful judicial review" of the claim? *Id*. Second, is the claim "wholly collateral" to the statute's review provisions? *Id*. Third, is the claim "outside the agency's expertise?" *Id*. Regarding that third consideration, it is worth noting that following *Axon* the Supreme Court gutted the notion of "agency expertise" in *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (2024).

There, the Supreme Court held "Chevron is overruled." *Id*. at 2247.

The Government, before reviewing these factors, first contends that the district court lacks jurisdiction under *Thunder Basin* and *Axon* because "the CSA's text, structure, and purpose plainly reflect Congress' intent to preclude district court jurisdiction for challenges such as Rifai's APA claims." (ECF No. 24 at 19); *see Adorers of the Blood of Christ v. FERC*, 897 F.3d 187, 195 (3d Cir. 2018) (holding the first step the court asks is whether Congress' intent to preclude district court jurisdiction is fairly discernible in the statutory scheme, based on an examination of the statute's text, structure, and purpose). But the Government fails to cite anything within the CSA, nor any case law, that supports this naked assertion. Instead, the Government cites to 21 U.S.C. § 877, which states as follows:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

21 U.S.C. § 877.

That Statute clearly specifies that final and conclusive decisions may be reviewed in the United States Court of Appeals for the District of Columbia or in the circuit where an individual's principal place of business is located. *Id.* Nothing in that Statute precludes judicial review on constitutional challenges. Indeed, the Supreme Court has made clear that Congress enacted the CSA to focus on and strengthen existing drug laws. *United States v. Moore*, 423 U.S. 122, 139 (1975). The CSA was never designed for, nor is it equipped to handle, the constitutional challenges that Dr. Rifai has levied. On this score, the Government is clearly mistaken.

Next, the Government argues that this Court does not have jurisdiction because Dr. Rifai's claims fall short of the three considerations the Supreme Court identified in *Thunder Basin*. Here,

the Government's arguments fare no better.

i. Will Precluding District Court Jurisdiction foreclose Dr. Rifai from all Meaningful Judicial Review?

The causes of action brought before this Court represent Dr. Rifai's challenges to the DEA's own existence and the administrative process that leads to agency action against medical professionals like Dr. Rifai. He challenges matters directly corresponding to his constitutional rights such as his Fourth and Fifth Amendment rights under the U.S. Constitution and the DEA's disregard for these. Under the Controlled Substance Act's statutory review scheme, judicial review is provided for in the Court of Appeals once the DEA has reached a final action. 21 U.S.C. § 877. So, it is possible that in the future Dr. Rifai will have the right to bring claims before the Court of Appeals as *Axon* and *Cochran* had the possibility to do the same. *Axon*, 598 U.S. at 191. However, the Supreme Court's inquiry in this consideration did not stop here. *Id*. Dr. Rifai's possibility of receiving review does not equate to him receiving "meaningful judicial review." The Supreme Court did not only consider whether at some point some another court could review the claims at issue, but instead also considered the timeliness of the review and the effects on the plaintiff's "here-and-now injury." *Id*. Dr. Rifai's here-and-now injury is being subjected to a DEA Administrator's final decision without a hearing. (ECF No. 17 at ¶ 64). Dr. Rifai's injury also stems from being subjected to this DEA administrative proceeding in the first place, which was used as a pretext to secure an administrative subpoena to gather evidence in a pending criminal case in violation of the Fourth Amendment. (ECF No. 17 at ¶¶ 50-61). These causes of action require review in the district court because they do not depend on the outcome of a proceeding before the DEA but rather the structure and process that has led Dr. Rifai to this situation.

The same was true in *Axon*, where the Supreme Court found that even if Axon ultimately had the order of the agency overturned, he had already been subjected to an "unconstitutional agency authority" based on a "proceeding by an unaccountable ALJ." *Id*. at 191. This led the Supreme Court to its

conclusion that Axon's case should be reviewed by the district court because once it arrived at the Court of Appeals it would be too late. *Id*. at 178 (Judicial review of *Axon's* (and *Cochran's*) structural constitutional claims would come too late to be meaningful.").

Dr. Rifai also requires meaningful review as to his injury from the DEA's self-made general standards which constitutes the unconstitutional broadening of its powers under the CSA. (ECF No.17, at 19-20). In relation to this, the Government sets forth the argument that Dr. Rifai offers no factual allegations demonstrating how these factors have been misused or how they will be misused in his own administrative case. (ECF No. 24 at 22). But the Government ignores the statements and observations from the DEA *Chief* Administrative Law Judge, Hon. John J. Mulrooney, describing how the DEA has strayed away from the specific instructions of the CSA and Supreme Court. [1] The government points to nothing to contradict Chief Judge Mulrooney's findings.

Instead, the Government contends that "Rifai does not identify the purportedly encroaching pre-2017 DEA final orders, so it is impossible to discern how the general practice standards were applied." ECF No. 24 at 22. It is evident that the Government did not read the article that Dr. Rifai cited from Chief Judge Mulrooney. There, Judge Mulrooney states as follows:

> In one such case, *Fiaz Afzal, M.D.*, the Agency accepted the findings and legal conclusions of a state medical board, which, in a decision that occurred after the close of the DEA administrative hearing, suspended the respondent's state medical privileges. In the course of its reliance on the state board, citing its own prior final orders and a criminal diversion case, the Agency held that:
>
> [T]he prescribing of a controlled substance (and the continued prescribing of a controlled substance) under the following circumstances establishes that a physician lacked a legitimate medical purpose and acted outside of the usual course of professional practice

[1] "Although [] the Supreme Court has unambiguously clarified that the authority to set medical standards rests exclusively with the states, and is nowhere within the purview of the DEA, some recent Agency final orders have embraced the application of what the Agency has termed 'general practice standards' in ascertaining whether a practitioner has acted in the course of a professional practice." John J. Mulrooney II and Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 385-86 (2017), https://scholarship.law.marquette.edu/mulr/vol101/iss2/3/.

> and therefore violated the CSA:
>
> •[w]ithout performing an appropriate physical examination,
>
> • without utilizing appropriate diagnostic testing,
>
> • failing to devise and document a written treatment plan,
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> • failing to periodically reassess the effectiveness of the treatment,
>
> • continuing to prescribe controlled substances without pursuing alternative therapies,
>
> • repeatedly and continually prescribing without referring the patient to appropriate specialists, and
>
> • failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications. [2]

The list of cases goes on, however. Chief Judge Mulrooney also cites to Grider Drug #1 & Grider Drug #2, 77 Fed. Reg. 44070, 44093 n.73 (Drug Enf't Admin. July 26, 2012); Bienvenido Tan, M.D., 76 Fed. Reg. 17673, 17681 (Drug Enf't Admin. Mar. 30, 2011); Jones Total Health Care Pharmacy, L.L.C., 81 Fed. Reg. 79188, 79190 (Drug Enf't Admin. Nov. 10, 2016); Hills Pharmacy, L.L.C., 81 Fed. Reg. 49816, 49837 (Drug Enf't Admin. July 28, 2016); and Wesley Pope, M.D., 82 Fed. Reg. 14944, 14976 (Drug Enf't Admin. Mar. 23, 2017). [3]

Here, Dr. Rifai has already been subject to these "general practice standards," which the DEA used in issuing him an Order to Show Cause on his DEA registration. (ECF No. 17 at ¶ 32). These are the same "general practice standards" that will inform the Administrator's decision on whether to revoke Dr. Rifai's DEA registration. And these are the same "standards" that have radiated though the entirety of the DEA, as evidenced in the chain of cases immediately above.

As the DEA continues to go unchallenged, it has only become more emboldened. And now, it is Administrative Law Judges who are dispensing with hearings altogether. Here, that has deprived Dr. Rifai of his Fifth Amendment right to due process. (*Id.* at ¶ 68). Accordingly, Dr. Rifai will be denied

[2] *Id.*
[3] *Id.*

"meaningful judicial review" [4] on the violation of his Fourth and Fifth Amendment rights should the Court dismiss his Amended Complaint and instead make him wait to appeal following the DEA Administrator's decision on revocation.

ii. Dr. Rifai's Constitutional Challenges are "Wholly Collateral" to the Statutory Review Provisions

Like in *Axon*, Dr. Rifai's constitutional claims are "wholly collateral" to the statute's review provisions. The Supreme Court held that the claims in *Axon* had "nothing to do with the enforcement-related matters the Commission's "regularly adjudicate [ ] and nothing to do with those they would adjudicate in assessing the charges against Axon and Cochran." 598 U.S. at 193. Similarly, here, Dr. Rifai's constitutional claims, (ECF No. 17 at ¶¶ 50-70), are not dependent on the outcome of the DEA Administrator's decision. These relate solely to Dr. Rifai's constitutional rights which have been violated, not the sort of matter that relates to the merits of these proceedings. Additionally, they are not matters that an agency such as the DEA usually resolves when determining whether to revoke a registrant's DEA registration to prescribe controlled substances. *See Axon,* 598 U.S. at 194 ("And unlike in Elgin, ruling for Axon and Cochran on expertise-laden grounds would not 'obviate the need' to address their constitutional claims – which, again, allege injury not from this or that ruling but from subjection to all agency authority").

Regardless of the ultimate decision that the DEA Administrator makes on revocation, Dr.

[4] The Government claims that the Court of Appeals for the Third Circuit is not a rubber stamp affirming the DEA's Administers decisions. ECF No. 24 at 20 n.4. But the Government cites to only one case where the Third Circuit reversed the DEA's decision revoking a physician's registration. It provides no other cases. Moreover, the Third Circuit can only set aside the DEA's order if it is found to be "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law." *See Humphreys v. DEA*, 96 F.3d 658, 660 (3d Cir. 1996). That is a highly deferential standard. And that standard is even more difficult to mount given that, as Chief Judge Mulrooney has observed, the DEA cites to its own "general practice standards" in revoking past registrant's DEA registrations to prescribe controlled substances. *See supra* Mulrooney at 385-86. The DEA, by citing to its own decisions subscribing to its "general practice standards," has insulated itself from the Third Circuit's deferential standard of review. *See Humphreys*, 96 F.3d at 663 ("An agency's action is arbitrary and capricious if the agency entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." (internal quotation marks and citation omitted)).

Rifai's constitutional claims will remain unresolved. Accordingly, Dr. Rifai is entitled to have the district court review his constitutional claims as they are "wholly collateral" to the review standards set forth in the APA and external to the inherent fabric of the DEA.

iii. Dr. Rifai's Constitutional Claims Fall Outside of the DEA's Subject Matter Expertise

As raised in previous pleadings, the DEA's mission and area of expertise is to bring before the justice system the organizations and its principals involved in the "growing, manufacture, or distribution of controlled substances for illicit traffic in the United States." [5]; *see also Moore*, 423 U.S. at 139 (finding Congress enacted the CSA to focus on and strengthen existing drug laws). The DEA's subject matter expertise falls outside that of constitutional inquiry. *See*, *Axon*, 598 U.S. at 194-95 (finding that agencies such as FTC and SEC are not experts in reviewing constitutional violations). Like *Cochran* and *Axon*, Dr. Rifai's "here-and-now" injury stems from the DEA's deprivation of his Fourth and Fifth Amendment rights, (ECF No. 17 at ¶¶ 50-70), as well as the DEA's continued broadening of its authority under the CSA. (*Id.* at ¶¶ 71-77).

The Government argues that Dr. Rifai's claims fall under the DEA's subject matter expertise because the "DEA's statutory enforcement regime plainly contemplates administrative law judges deciding routine adjudicatory questions such as whether attorney misconduct warrants a sanction and the nature of the sanction." (ECF No. 24 at 21). The Government is mistaken. These matters are not within the DEA's subject matter expertise when they have been conducted in a way to violate a registrant's Fourth and Fifth Amendment rights. However, even if the Government were correct, the Supreme Court has done away with the notion of "agency expertise." *Loper Bright Enters*, 144 S. Ct. at 2247.

Accordingly, Dr. Rifai respectfully submits that the causes of action in his Amended

[5] https://www.dea.gov/who-we-are/about.

Complaint qualify for subject matter jurisdiction under *Thunder Basin* and *Axon*.

II. DR. RIFAI'S ALLEGATIONS REGARDING THE VIOLATION OF HIS FOURTH AMENDMENT RIGHT ARE NOT MOOT

The Government again claims that the Court should dismiss Count 1 alleging the violation of the Fourth Amendment because the Court lacks subject-matter jurisdiction. (ECF No. 24, at 20). The Government contends that because Dr. Rifai's Fourth Amendment claim is grounded in his criminal prosecution where the Government improperly used an administrative subpoena to obtain medical records, an injunction against the DEA's administrative proceedings will not remedy any alleged harm. *Id*. According to the Government the Court should thus dismiss Dr. Rifai's Amended Complaint. *Id*.

The Government is mistaken. An administrative agency cannot enforce its regime in violation of the Constitution. That represents a "here-and-now injury." *Axon*, 598 U.S. at 191 (citation omitted). Dr. Rifai is moving that the Court abolish the DEA's unconstitutional practice of violating the Fourth Amendment and leveraging administrative subpoenas to obtain evidence to be used in a criminal prosecution. *See*, *United States v. Hossbach*, 518 F. Supp. 759, 766-67 (E.D. Pa. 1980). Dr. Rifai is also moving for the Court to exclude from the DEA administrative process any evidence that was obtained from the illegitimate subpoena. *See*, *Herring v. United States*, 555 U.S. 135, 141 (2009) (finding that the exclusionary rule is appropriate where it results in appreciable deterrence).

Here, by applying the exclusionary rule and excluding the Government's "ill-gotten gains," the Court can ensure that other registrant's do not fall prey to the DEA's unconstitutional use of administrative subpoenas. Use of the rule is particularly important in this context too because it will dissuade the DEA from pursuing frivolous revocation proceedings against registrants to obtain evidence for criminal prosecution. Because patients rely on registrants to obtain the medications

that they require for their medical care, deterrence is a must in this context. *See*, *Boynes v. Limetree Bay Ventures LLC*, No. 23-2432, 2024 U.S. App. LEXIS 19467, at *9 (3d Cir. Aug. 5, 2024) (finding the district court correctly found that the balance of the equities and the public interest both favor the plaintiffs where there was a strong health interest in access to safe drinking water).

To the extent that the Government may claim that the DEA does not intend to use the ill-obtained evidence, that proves Dr. Rifai's point: That the DEA never intended to use the evidence during the administrative process but instead improperly used an administrative subpoena to obtain evidence for the Government's criminal prosecution of Dr. Rifai. *See*, (ECF No.17, at 14-16).

The Court thus has subject-matter jurisdiction, and it should deny the Government's request to dismiss under Rule 12(b)(1).

III. THE REMOVAL OF DEA ALJS IS UNCONSTITUTIONAL

The Government alleges that Dr. Rifai has dropped his claims concerning the constitutionality of DEA ALJ Appointments and Removal Statute due to not alleging them in his Amended Complaint. (ECF No. 24 at 23). The Government, however, fails to cite any supporting case law to point that these claims are dropped. Dr. Rifai submits to the Court that the claims related to the deficiencies in the appointment of ALJs and the statute governing their removal are present in his Amended Complaint. (ECF No. 17 at ¶¶ 18-22). Indeed, contained in his Amended Complaint is the pertinent case law on appointment and removal. See (ECF No. 17 at ¶ 19).

If the Court finds that the claims under this matter were dropped, then Dr. Rifai will move to respectfully request the Court's permission to file a Second Amended Complaint. Pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure, a party is permitted to request the court's leave to amend its pleading when the amendment can no longer be brought as a matter of course. Fed. R. Civ. P. 15(a)(2). This rule also provides that the Court should "freely give leave when

justice so requires." *Id.*; *See, e.g., Kern v. Phoenixville Hosp., LLC*, 342 F.R.D. 324, 331 (E.D. Pa. 2022) ("Defendant has failed to demonstrate that undue delay, bad faith, dilatory motives, futility, or prejudice should bar Plaintiff from amending her First Amended Complaint. Moreover, Plaintiff's proposed amendments relate back to Plaintiff's initial Complaint. Accordingly, leave to amend is granted.").

Here, Dr. Rifai seeks to amend his Amended Complaint to re-allege the appointment and removal issues he raised in his initial Complaint. (*See* ECF No. 1 ¶¶ 52-57). The Government was contacted for their position on the sought-after amendment and the Government indicated that they oppose any further amendment. However, Dr. Rifai's amendment in a Second Amended Complaint would not prejudice the Defendants. The cause of action is one that the Defendants have had the opportunity to respond to twice since the initiation of this action and, in fact, they did respond to this claim in their Motion to Dismiss the Initial Complaint. (ECF No. 16 at 21-24). Also, the Defendants addressed this cause of action in their Motion to Dismiss the Amended Complaint and again incorporated their previous arguments presented to this Court. (ECF No. 24 at 23-24). Therefore, the Defendants would not be blindsided by this amendment, nor would they be prejudiced as they have had previous notice and multiple opportunities to respond, and in fact have responded. Dr. Rifai, further, adopts by reference the previous arguments he made on removal in his first response to the Government's Motion to Dismiss Complaint. (ECF No. 21 at 10).

CONCLUSION

For the foregoing reasons, Dr. Rifai respectfully asks that the Court deny the Government's Motion to Dismiss Amended Complaint.

Respectfully submitted,
CHAPMAN LAW GROUP

Dated: December 2, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2024, I electronically filed the forgoing document with the clerk of court by using the CM/ECF system which will send the notice of electronic filing to all attorneys of record.

/s/ *Ronald W. Chapman, II*
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